

Application No. 09/774,284  
Amendment Dated 08/09/2004  
Reply to Office Action of 03/09/2004

### **REMARKS/ARGUMENTS**

For the convenience of the Examiner and the PTO, all reference to amendments to the specification and support for new claims relate to the paragraph numbering of the publication of the present application, US 2001/0034435A1.

#### **I. Amendments to the Specification:**

In paragraph [0021], the following amendment is introduced to provide a chemical and structural definition of the claimed anion exchange resin, described by its trade name in the specification as TMAE Fractogel 650S: "TMAE Fractogel 650S is a tentacle ion exchanger having trimethylaminoethyl functional groups (TMAE) covalently attached to hydroxyl groups of a synthetic methacrylate based polymeric resin backbone." This description is abstracted from the manufacturer's brochure provided in the presently submitted Supplemental IDS and was known to those of skill in the art at the time of filing of the application. No new matter is introduced by this amendment.

#### **II. Status of the Claims and Amendments:**

Claims 1 - 103 and 105 - 108 have been cancelled and new claims 115 - 121 have been added. The new claims do not introduce new matter. Support for the new claims can be found throughout the specification and drawings as originally found. For example, support for use of a tentacle strong anion exchange resin having a TMAE functional group can be found, among other places, in paragraphs [0021], [0031], [0045], [0049 - 51], [0061 - 62], and [0077].

#### **III. Rejections under 35 U.S.C. § 102**

All claims rejected under §102 have been cancelled with the exception of claim 104 which has been amended to include a limitation to tentacle anion exchange chromatography, which the Examiner concedes was not taught by Wan.

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#### **IV. Rejections under 35 U.S.C. § 103**

While not conceding the Examiner's determination of obviousness of all prior pending claims, in order to advance the prosecution of the present case all prior rejected claims have been either cancelled or amended. New claims have been added to clarify the claimed invention.

All present pending claims are directed to plasmid purification using tentacle anion exchange resins with dependent claims to use of a resin having a trimethylaminoethyl (TMAE) functional group. This functional group forms a strong anion exchanger. Because DNA is an anion, strong anion exchangers were avoided in some plasmid purification protocols because the plasmid DNA could be difficult to recover from the column. *See, e.g.* AU199721661B2, Australian English language counterpart of WO97/35002, entitled "Purification of Pharmaceutical-Grade Plasmid DNA", included in the present Supplemental IDS.

Applicant surprisingly found that ion exchange chromatography of plasmid DNA solutions using the TMAE tentacle anion exchange resin, exemplified by TMAE Fractogel 650 resulted in significant purification and that the capacity of the resin made it suitable for large scale manufacturing. Applicant believes the present application to teach the first use of tentacle based anion exchangers, and particularly TMAE anion exchanger, in plasmid purification. Neither the cited Wan or Kasai reference teaches or suggests tentacle anion exchange chromatography for plasmid purification.

To the extent the independent claims are patentable, the dependent claims are have been similarly placed in condition for allowance.

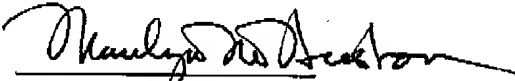
#### **Conclusion**

For the reasons stated herein, the Applicant respectfully submits that independent claims 104 and 115 are allowable and that the dependent claims are, in turn, also allowable. Applicant respectfully requests allowance of the claims at an early date. The Commissioner is authorized to charge any additional fees incurred in this application or credit any overpayment to Deposit

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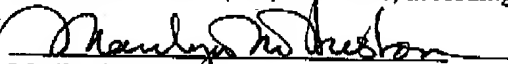
Account No. 50-1922. Should the Examiner have any questions, please do not hesitate to call Applicant's attorney at 832-446-2421.

Respectfully submitted,

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Marilyn M. Huston